

CONSTRICKTION DEVICE VIEWABLE UNDER X RAY FLUOROSCOPY

BACKGROUND OF THE INVENTION

[1] The present invention is generally directed to a constricting device that constricts body tissue. The present invention is more particularly directed to a constricting device which is viewable under X ray fluoroscopy.

[2] Constriction devices have been contemplated for constricting body tissue. Such devices have been considered for use, for example, in tissue resection procedures and in treating pulmonary disease.

[3] Chronic Obstructive Pulmonary Disease (COPD) has become a major cause of morbidity and mortality in the United States over the last three decades. COPD is characterized by the presence of airflow obstruction due to chronic bronchitis or emphysema. The airflow obstruction in COPD is due largely to structural abnormalities in the smaller airways. Important causes are inflammation, fibrosis, goblet cell metaplasia, and smooth muscle hypertrophy in terminal bronchioles.

[4] The incidence, prevalence, and health-related costs of COPD are on the rise. Mortality due to COPD is also on the rise. In 1991 COPD was the fourth leading cause of death in the United States and had increased 33% since 1979.

[5] COPD affects the patient's whole life. It has three main symptoms: cough; breathlessness; and wheeze. At first, breathlessness may be noticed when running for a bus, digging in the garden, or walking up hill. Later, it may be noticed when simply walking in the kitchen. Over time, it may occur with less and less effort until it is present all of the time.

[6] COPD is a progressive disease and currently has no cure. Current treatments for COPD include the prevention of further respiratory damage, pharmacotherapy, and surgery. Each is discussed below.

5 **[7]** The prevention of further respiratory damage entails the adoption of a healthy lifestyle. Smoking cessation is believed to be the single most important therapeutic intervention. However, regular exercise and weight control are also important. Patients whose symptoms restrict their daily activities or who 10 otherwise have an impaired quality of life may require a pulmonary rehabilitation program including ventilatory muscle training and breathing retraining. Long-term oxygen therapy may also become necessary.

15 **[8]** Pharmacotherapy may include bronchodilator therapy to open up the airways as much as possible or inhaled β -agonists. For those patients who respond poorly to the foregoing or who have persistent symptoms, Ipratropium bromide may be indicated. Further, courses of steroids, such as corticosteroids, may be required. Lastly, antibiotics may be required to prevent 20 infections and influenza and pneumococcal vaccines may be routinely administered. Unfortunately, there is no evidence that early, regular use of pharmacotherapy will alter the progression of COPD.

25 **[9]** Lung transplantation is also an option. Today, COPD is the most common diagnosis for which lung transplantation is considered. Unfortunately, this consideration is given for only those with advanced COPD. Given the limited availability of donor organs, lung transplant is far from being available to all patients.

[10] About 40 years ago, it was first postulated that the tethering force that tends to keep the intrathoracic airways open was lost in emphysema and that by surgically removing the most affected parts of the lungs, the force could be partially
5 restored. Although the surgery was deemed promising, the procedure was abandoned.

[11] The lung volume reduction surgery (LVRS) was later revived. In the early 1990's, hundreds of patients underwent the procedure. However, the procedure has fallen out of favor due to
10 the fact that Medicare stopped remitting for LVRS. Unfortunately, data is relatively scarce and many factors conspire to make what data exists difficult to interpret. The procedure is currently under review in a controlled clinical trial. However, what data does exist tends to indicate that patients benefited from the
15 procedure in terms of an increase in forced expiratory volume, a decrease in total lung capacity, and a significant improvement in lung function, dyspnea, and quality of life.

[12] Improvements in pulmonary function after LVRS have been attributed to at least four possible mechanisms. These include
20 enhanced elastic recoil, correction of ventilation/perfusion mismatch, improved efficiency of respiratory musculature, and improved right ventricular filling.

[13] The improvements in pulmonary function resulting from LVRS cannot be ignored. However, the surgery is very invasive and
25 fraught with complications. Among the complications is the potential for lung air leaks. Lung tissue is very thin, and fragile hence difficult to suture together. After a lung portion is sectioned and removed, the remaining lung is most often restructured with suture staples. In about thirty percent (30%)

of the cases, the difficulty with suturing lung tissue results in air leaks. Treatment for such air leaks depends upon their severity and often, in the most serious cases, requires further open chest surgery.

5 [14] Air leaks in lungs can be caused by other causes. With increasing age, a patient may develop a weakened section of lung which may then rupture due to an extreme pressure differential, such as may result from simply a hard sneeze. AIDS patients can suffer from air leaks in their lungs. Air leaks in lungs can
10 further be caused by a puncture from a broken rib or a stab wound.

15 [15] The invention disclosed and claimed in copending United States Application Serial No. 09/534,244, ⁴¹ incorporated herein by reference, provides an improved therapy for treating COPD and air leaks in lungs. The therapy includes a constriction device which, when deployed on a lung, suppresses air leaks in the lung tissue without requiring any suturing of the effected lung tissue. Still further, by constricting a large enough portion of a lung with the device, lung volume reduction with the concomitant improved pulmonary function may be obtained without the need for any
20 suturing of lung tissue at all.

25 [16] The lung constriction device includes a jacket or sheath of flexible material configured to cover at least a portion of a lung. The jacket has a pair of opened ends to permit the lung portion to be drawn into the jacket. The jacket is dimensioned to constrict the lung portion after the lung portion is drawn therein. The lung constriction device is preferably formed of expandable, such as elastic, material for receiving the lung tissue while the device is in an expanded or enlarged condition, and then contractible about the lung portion upon

release of the expanded condition for constricting the lung tissue.

[17] An important aspect of the device and method disclosed in United States Application Serial No. 09/534,244 is the ability 5 to sever the constricting device intermediate its ends. This allows a significant portion of the constricted lung tissue to be removed altogether while permitting a portion of the constricting device to remain in the body for continued suppression of air leaks and maintenance of the remaining lung tissue integrity.

10 [18] Devices and methods similar to those disclosed in United States Application Serial No. 09/534,244 may be employed to advantage in other and different procedures such as in general resection procedures and for body tissue other than lung tissue. Resection procedures are commonly performed for such body tissue 15 as, for example, atrial appendage tissue, ovarian tissue, gall bladder tissue, pancreatic tissue, appendix tissue and spleen tissue. Resection procedures may be required to treat cancer, organ damage, or organ disease, for example.

19 [19] United States Application Serial No. 09/534,244 also 20 discloses and claims various methods and apparatus for deploying the constricting device on body tissue such as lung tissue. One apparatus and method contemplates mechanically expanding the device in a transverse dimension while physically pulling the tissue to be constricted into the device.

25 [20] Another method contemplates mounting the device over a vacuum chamber and pulling the tissue into the vacuum chamber by engaging the tissue with an opened end of the chamber and then drawing a vacuum in the chamber. This draws the tissue into the

chamber. Then, the chamber is withdrawn from the device, leaving the tissue constricted in the device.

[21] A further method contemplates inserting the device into a vacuum chamber and sealing the opened end of the chamber to the 5 device. The opened end of the chamber and the tissue are then brought into sealing engagement. A vacuum is next pulled in the chamber and the device to pull the tissue into the device and chamber. Once the tissue is within the device, the chamber is removed from over the device leaving the tissue constricted in the 10 device.

[22] United States application Serial No. (case 1759-7), incorporated herein by reference, discloses and claims another apparatus and method for deploying a constriction device on body tissue. Dual vacuums allow higher constriction volumes and higher 15 applied constriction forces.

[23] The apparatus includes an elongated housing that receives the constriction device longitudinally therein. A first opening sealable to a first opening of the device and a second opening sealable to a second opening of the device forms a sealed 20 space external to the device within the housing. The apparatus further includes a first vacuum source that pulls a first vacuum within the sealed space, and a second vacuum source that pulls a second vacuum through the second opening when the body tissue is brought into engagement with the first opening of the device.

25 The first vacuum serves to expand the device while the second vacuum serves to pull the body tissue into the device.

[24] Although various methods and apparatus have been conceived for effectively deploying constriction devices on body tissues, the constriction devices, over time, may become

dislodged due to the nature of the soft tissue on which they are deployed. More specifically, soft body tissue has a tendency to expand at the proximal end of the device causing longitudinal slippage of the device on the body tissue. This may eventually 5 lead to the device slipping totally free from the tissue. Hence, there is a need for additional constriction device structure for fixing the device on the tissue.

[25] In addition, some contemplated uses of the constriction devices, such as in effecting a reduction in lung volume, require 10 that the device remain on the tissue for an indeterminate period of time. Once the patient has recovered from the deployment procedure, it would be helpful to be able to determine that the device has remained in position. Hence, there is a need for such a device to be visible by the physician in some manner long after 15 the deployment procedure has taken place.

[26] The present invention addresses these needs. It provides a constriction device having positive fixation structure for maintaining the constriction device deployed on the body tissue. The present invention further renders it possible to 20 determine the position of the device within the body to permit medical personnel to confirm that the device has remained in place and that it continues to be effective. In accordance with particular aspects of the present invention, it is the fixation structure which also renders it possible to determine the 25 position of the device.

SUMMARY OF THE INVENTION

[27] The invention provides a constriction device that constricts body tissue and which is visible under X ray

fluoroscopy. The device includes an elongated sleeve having opposed opened ends and being formed from expandable material to receive therein, when in an expanded condition, body tissue to be constricted and to constrict the body tissue therein when

- 5 released from the expanded condition. At least a portion of the sleeve is visible under X ray fluoroscopy.

[28] The sleeve further includes an outer surface and a coating of X ray opaque material on the outer surface to form the portion of the sleeve visible under X ray fluoroscopy. The

- 10 sleeve also has a longitudinal dimension between the opposed opened ends and the coating of X ray opaque material may include strips of X ray opaque material along the longitudinal dimension of the sleeve. Alternatively, the X ray opaque material may be embedded in the side wall to form the portion of the sleeve
15 visible under X ray fluoroscopy. The embedded X ray opaque material may be configured in strips extending within the sleeve side wall along the longitudinal dimension of the sleeve.

- [29] The sleeve may further include an inner surface and X ray opaque material may be on the inner surface to form the
20 portion of the sleeve visible under X ray fluoroscopy. The X ray opaque material may again be configured as strips of X ray opaque material along the longitudinal dimension of the sleeve.

- [30] The sleeve may include a plurality of X ray opaque elements to form the portion of the sleeve visible under X ray
25 fluoroscopy. The X ray opaque elements may be adjacent to one of the opposed openings and in a side-by-side relation.

BRIEF DESCRIPTION OF THE DRAWINGS

[31] The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further objects and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like reference numerals identify identical elements, and wherein:

[32] FIG. 1 is a simplified sectional view of a thorax illustrating a respiratory system having a constricting device embodying the present invention deployed on a portion of a lung to effect lung volume reduction;

[33] FIG. 2 is a sectional view similar to FIG. 1 but illustrating the respiratory system after the constricted lung portion has been resected;

[34] FIG. 3 is a perspective view illustrating a constricting device embodying the present invention;

[35] FIG. 4 is a side view of a constriction device including X ray visible elements in accordance with another embodiment of the present invention;

[36] FIG. 5 is a sectional view taken along lines 5-5 of FIG. 4;

[37] FIG. 6 is a perspective view of another constriction device embodying the present invention having fixation elements on an inside surface thereof wherein the fixation elements may be formed of material visible under X ray fluoroscopy in accordance with the present invention;

[38] FIG. 7 is a perspective view of another constriction device embodying the present invention;

[39] FIG. 8 is a perspective view of fixation elements which may be employed in accordance with the present invention;

[40] FIG. 9 is a perspective view of another constriction device embodying the present invention;

5 [41] FIG. 10 is a partial end view of the constriction device of FIG. 10 illustrating the manner in which the fixation elements function prior to the collapse of the constriction device;

10 [42] FIG. 11 is another partial end view of the constriction device of FIG. 10 illustrating the manner in which the fixation elements grasp the constricted tissue upon collapse of the constriction device;

[43] FIG. 12 is a sectional side view of another constriction device embodying the present invention;

15 [44] FIG. 13 is a side view of a mandrel which may be used in making the constriction device of FIG. 13; and

[45] FIG. 14 is a sectional side view of the mandrel of FIG. 13 at an intermediate stage in the making of the constriction device of FIG. 13.

20

DETAILED DESCRIPTION

[46] Referring now to FIG. 1, it is a sectional view of a respiratory system 20. The respiratory system 20 resides within the thorax 22 which occupies a space defined by the chest wall 24 and the diaphragm 26.

[47] The respiratory system 20 includes the trachea 28, the left mainstem bronchus 30, the right mainstem bronchus 32, and the bronchial branches 34, 36, 38, 40, and 42. The respiratory system 20 further includes left lung lobes 52 and 54 and right

lung lobes 56, 58, and 60. Each bronchial branch communicates with a respective different portion of a lung lobe, either the entire lung lobe or a portion thereof.

[48] A healthy respiratory system has an arched or inwardly arcuate diaphragm 26. As the individual inhales, the diaphragm 26 straightens to increase the volume of the thorax 22. This causes a negative pressure within the thorax. The negative pressure within the thorax in turn causes the lung lobes to fill with air to an inflated condition. When the individual exhales, the diaphragm returns to its original arched condition to decrease the volume of the thorax. The decreased volume of the thorax causes a positive pressure within the thorax which in turn causes exhalation of the lung lobes.

[49] FIG. 1 also shows a constriction device 70 embodying the present invention deployed on lobe 58. The device 70 is configured as a sleeve or sheath formed of a sheet of flexible or elastic biocompatible material. The material may be formed from silicone rubber, polyurethane, expanded polytetraflouroethylene, polyester and polyurethane, or nylon and polyurethane, for example. It may alternatively be flexible but nonexpandable formed from nylon, polytetraflouroethylene, or polyester, for example. If the sleeve is expandable, it may more specifically be formed from a sheet or fabric of 70% nylon and 30% polyurethane. The sleeve is preferably opened at both ends and may be generally cylindrical in configuration.

[50] As will be seen subsequently, in accordance with the preferred embodiment of the present invention, the sleeve is applied to the lung lobe while in an expanded condition. This may be accomplished, as disclosed in United States patent

application Serial No. (case 1759-7), by expanding the sleeve with a first vacuum and then pulling the lung portion into the sleeve with a second vacuum. When the lung portion is within the sleeve, the expansion of the device is released. With the
5 expansion released, the sleeve is permitted to contract or collapse about the lung portion to constrict the lung portion.

[51] The device 70 may be employed, for example, to suppress air leakages in lungs. It may also find use to advantage in constricting a lung portion suffering from COPD to simulate or
10 achieve lung volume reduction. All of the beneficial effects of lung volume reduction surgery may be realized and, most importantly, without requiring suturing of lung tissue.

[52] In accordance with the present invention, the constriction device 70 includes a plurality of coated strips 71 on the outer surface of the device 70. The strips are formed from gold, for example, to render the device visible under X ray fluoroscopy. This makes it possible for the physician to confirm at a later time that the device has maintained its position on the lung tissue 58.

20 [53] FIG. 2 shows the respiratory system 20 after the constricted lung portion has been resected. The device 70 is preferably formed of severable material, such as, any of the materials previously described. This enables the device 70 to be severed or cut intermediate its ends with a suitable bladed
25 instrument to resection the lung lobe 58. The portion of the device 70 remaining on the lobe 58 continues to constrict the lung tissue therein to form an effective seal from leakage. The strips 71 are coated on the device 70 to extend from the proximal end of the device. This enables at least portions of the strips

71 to remain after resectioning to permit the device to be visible under X ray fluoroscopy for future confirmation that the device 70 remains in place on the lung tissue. Hence, lung volume reduction is rendered an available treatment while 5 negating the need of conventional lung sectioning and suturing thus avoiding the potentially severe complications which accompany those procedures.

[54] FIG. 3 illustrates the constricting device 70 in greater detail. The device 70 is a generally cylindrical sleeve 10 having a longitudinal dimension 72 and a transverse dimension 74. As previously mentioned, the device 70 is preferably formed of an elastic material permitting the device to expand in the longitudinal dimension and more importantly in the transverse dimension. The device 70 has opposed opened ends 76 and 78. The 15 device may further include at each end 76 and 78 an integral rim 80 and 82 respectively.

[55] The strips 71 of X ray opaque material extend longitudinally along the outer surface of the device 70. The strips 71 also extend from the opening 78 which, when deployed on 20 the lung tissue 58, is at the proximal end of the device. This enables the strips 71 to remain on the device within the patient's body even though the device may be severed for resectioning the lung tissue or any other tissue on which the device 70 is deployed.

25 [56] FIGS. 4 and 5 illustrate another constriction device 90 embodying the present invention. Like the device 70, the device 90 is a sleeve generally cylindrical in configuration having opposed opened ends 92 and 94. Embedded within the longitudinal side wall 96 of the device 90, and extending longitudinally there

along, are a plurality of strips 98 of X ray opaque material. The strips 98, again, may be formed of gold, for example, or any other material known in the art which is visible under X ray fluoroscopy.

5 [57] Like the strips 71 of the device 70, the strips 98 of the device 90 extend from an opened end 92. By extending longitudinally, the strips 98 permit the device 90 to expanding transversely or radially outwardly during the deployment of the device 90. Once the device collapses about the tissue to be
10 constricted, the strips may be seen under X ray fluoroscopy to confirm its position with the patient's body.

[58] FIG. 6 illustrates another constriction device 100 embodying the present invention. The device 100 again is a generally cylindrical sleeve having opposed opened ends 102 and 104. Adjacent the opened end 102 and on the inner surface 106 of the sleeve are a plurality of fixation elements 108. In accordance with this embodiment, the fixation elements are elongated bars arranged adjacent each other and circumscribing the opening 102. The fixation elements are closely spaced. When
20 the device 100 is expanded to receive the tissue to be constricted, the tissue at least partially fills the spaces between adjacent fixation elements. Then, when the device 100 is permitted to collapse about the tissue to be constricted, adjacent fixation elements move toward each to grasp the tissue.
25 This provides positive fixation of the device on the constricted tissue and serves to resist migration or movement of the device in a longitudinal direction to maintain the device in a fixed position on the tissue.

[59] The fixation elements 108 are preferably formed of an X ray opaque material such as gold or stainless steel, for example. Again, this makes it possible to discern the position of the device 100 under X ray fluoroscopy. Hence, in accordance with 5 this embodiment, the fixation elements served a dual purpose, fixing the device 100 on the constricted tissue and rendering at least a portion of the device visible under X ray fluoroscopy.

[60] FIG. 7 illustrates another constriction device 110 embodying the present invention. The device 110 again is a 10 generally cylindrical sleeve having opposed opened ends 112 and 114. Adjacent the opened end 112 and on the inner surface 116 of the sleeve are a plurality of fixation elements 118. In accordance with this embodiment, the fixation elements take the form of wires or elongated pins. The fixation elements are 15 arranged adjacent each other and circumscribe the opening 112. The fixation elements are closely spaced and function in the same manner as the fixation bars 108. Hence, when the device 110 is expanded to receive the tissue to be constricted, the tissue at least partially fills the spaces between adjacent pins. Then, 20 when the device 110 is collapsed about the tissue to be constricted, adjacent pins move toward each to grasp the tissue. This again provides positive fixation of the device on the constricted tissue.

[61] Again, the pins 118 are preferably formed of an X ray 25 opaque material such as gold or stainless steel, for example. This makes it possible to discern the position of the device 100 under X ray fluoroscopy. Hence, in accordance with this embodiment, the pins serve the dual role of fixing the device 110

on the constricted tissue and rendering at least a portion of the device visible under X ray fluoroscopy.

[62] As may be best seen in FIG. 8, the pins 118 may be provided with projecting barbs 119. The barbs 119 promote the 5 grasping of the constricted tissue and provide additional gripping action for maintaining the device 110 in a fixed position once deployed.

[63] FIG. 9 illustrates still another constriction device 120 embodying the present invention. Again, the device 120 is a 10 generally cylindrical sleeve having opposed opened ends 122 and 124. Adjacent the opened end 122 and on the inner surface 126 of the sleeve are a plurality of fixation elements 128. In accordance with this embodiment, the fixation elements are generally square shaped pads arranged in rows adjacent each other and circumscribing the opening 122. As in the previous 15 embodiments, the fixation elements are closely spaced. As may be best seen in FIG. 10, when the device 120 is expanded to receive the tissue 58 to be constricted, the tissue at least partially fills the spaces, such as space 129, between adjacent fixation 20 elements. Then, when the device 120 is permitted to collapse about the tissue to be constricted as may best be seen in FIG. 11, adjacent fixation elements 128 move toward each other to grasp the tissue. This again provides positive fixation of the device on the constricted tissue and serves to resist migration 25 or movement of the device in a longitudinal direction to maintain the device in a fixed position on the tissue.

[64] The fixation elements 128 are again preferably formed of an X ray opaque material such as gold or stainless steel, for example. Again, this makes it possible to discern the position

of the device 100 under X ray fluoroscopy. Hence, the fixation elements 128 fix the device 120 on the constricted tissue and render at least a portion of the device 120 visible under X ray fluoroscopy.

5 [65] As may also be noted in FIGS. 10 and 11, the fixation elements 128 may be provided with a roughened surface 127. This further promotes gripping of the tissue 58 by the fixation elements 128.

[66] FIG. 12 illustrates another constriction device 130 embodying the present invention. Again, the device 130 is a generally cylindrical sleeve having opposed opened ends 132 and 134. In accordance with this embodiment, the fixation elements are integral to and within the longitudinal side wall 136 of the device 130. More specifically, the fixation elements take the form of integral protrusions 138 extending inwardly from the inner surface 135 of the device 130. The protrusions 138 serve to grasp the constricted tissue when the device is permitted to collapse about the tissue.

[67] FIG. 13 illustrates a mandrel 140 which may be used in making the constriction device 130 of FIG. 12. The mandrel 140 is generally cylindrical in configuration and includes on its outer surface 142 a plurality of semispherical indentations or divots 144.

[68] The device 130 may be made by using the mandrel 140 in a dipping process. Here, the mandrel is dipped into a liquid material, such as liquid silicone rubber which is elastic when hardened. After at least two such dips, the assembly of FIG. 13 will appear as shown in FIG. 14. The mandrel 140 is now covered by a silicone rubber film. Into each semispherical divot of the

film a hardened or solid sphere 148 is placed. Then, the assembly of FIG. 14 is once again subjected to multiple additional dips into the liquid silicone rubber until the side wall of the device 130 is built up to a suitable thickness, such 5 as, for example, .015 inches. The resulting film is then permitted to harden. Once hardened, the end panels are cut away to form the opposed opened ends 132 and 134 and the film is removed from the mandrel. What remains is the device 130 of FIG. 12.

10 [69] Preferably, the solid spheres 148 are formed of a material opaque to X rays. Such a material may, for example, be gold or stainless steel. This renders the device 130 at least partially visible under X ray fluoroscopy. As a result, the device 130 is provided with a fixation structure in the form of 15 integral protrusions 138 while also being provided with X ray visible elements.

20 [70] While the invention has been described by means of specific embodiments and applications thereof, it is understood that numerous modifications and variations could be made thereto by those skilled in the art without departing from the spirit and scope of the invention. It is therefore to be understood that within the scope of the claims, the invention may be practiced otherwise than as specifically described herein.